

Ministry of Health

COVID-19 Vaccine Information Sheet

Pfizer-BioNTech COVID-19 Vaccine

Version 1 – December 12, 2020 (amended December 13, 2020)

This information sheet provides basic information only. It is not intended to provide or take the place of medical advice, diagnosis or treatment. For more information about the Pfizer-BioNTech COVID-19 Vaccine, please refer to the product monograph authorized by Health Canada.

Please read this information sheet carefully and ensure all your questions have been answered by a health care provider before receiving the vaccine. The Pfizer-BioNTech has been evaluated and authorized for use in Canada by Health Canada, using rigorous standards. Health Canada will continue to monitor to ensure it is safe and effective.

In the event of any conflict between this guidance document and any applicable emergency orders, or directives issued by the Minister of Health, Minister of Long-Term Care, or the Chief Medical Officer of Health (CMOH), the order or directive prevails.

- Please check the Ministry of Health (MOH) [COVID-19 website](#) regularly for updates to this document, list of symptoms, other guidance documents, Directives and other information.

What is COVID-19?

- COVID-19 is an infection caused by a new coronavirus (SARS-CoV-2). COVID-19 was recognized for the first time in December 2019 and has since spread around the world to cause a pandemic. COVID-19 is mainly passed from an infected person to others when the infected person coughs, sneezes, sings, talks or breathes. It is important to note that infected people can spread the infection even if they have no symptoms.

- [Symptoms of COVID-19](#) can include cough, shortness of breath, fever, chills, tiredness and loss of smell or taste. Some people infected with the virus have no symptoms at all, while others have symptoms that range from mild to severe.
- [Of people diagnosed with COVID-19 in Canada](#), about 1 in 13 require hospitalization and about 3 out of every 100 people diagnosed with COVID-19 die. Even people with mild symptoms may feel unwell for a long time after a COVID-19 infection.

How does the Pfizer -BioNTech vaccine protect against COVID-19?

All vaccines work by presenting our body with something that looks like the infection so that our immune system can learn how to produce natural protection. This natural protection then helps to keep us from becoming sick if we come into contact with the real virus in the future.

This Pfizer-BioNTech COVID-19 vaccine uses a method called messenger RNA (mRNA). The mRNA is like a code that tells the cells in your body how to make a piece of the outer lining of the virus, for a short time. This piece of the virus cannot hurt you, but it is enough for your immune system to learn how to recognize and be ready to fight off the virus. In a large study where people were given 2 doses of this vaccine, the vaccine was shown to work very well at preventing people from becoming sick with COVID-19. The immunized group of people were 95% less likely to become sick with COVID-19 compared to the group that did not receive the vaccine. You cannot get COVID-19 from the vaccine.

Who can receive this vaccine and who cannot?

A complete vaccine series (2 doses of vaccine given 21 days apart) should be offered to individuals who are 16 years of age and older without contraindications to the vaccine.

If you have any [symptoms that could be due to COVID-19](#), you should not receive the vaccine at this time. You should wait 14 days after receiving any other vaccine before receiving the COVID-19 vaccine.

Talk with your health care provider or where available, call Telehealth Ontario (1-866-797-0000) about your symptoms and getting a COVID-19 test. Your health care provider will advise you when you are able to receive the vaccine.

See **Table 1** below for more details regarding who should not get this vaccine.

Who should not receive the vaccine	Precautions should be taken with:
<p>The Pfizer-BioNTech COVID-19 vaccine is contraindicated in:</p> <ul style="list-style-type: none"> • Individuals with a history of anaphylaxis after previous administration of the vaccine. • Persons with proven immediate or anaphylactic hypersensitivity to any component of the vaccine or its container, including polyethylene glycol. • Vaccination should be deferred in symptomatic individuals with confirmed or suspected SARS-CoV-2 infection, or those with symptoms of COVID-19. To minimize the risk of COVID-19 transmission, symptomatic individuals who arrive at an immunization clinic/ venue, should be instructed to follow current local public health measures, and be encouraged to get tested. • Acutely ill individuals: As a precautionary measure • Individuals who have received another vaccine (not a COVID-19 vaccine) in the past 14 days. <p>Individuals who are immunosuppressed due to disease or treatment or those with an autoimmune disorder until further evidence is available as they were excluded from the clinical trials.</p>	<ul style="list-style-type: none"> • Patients who have a bleeding problem, bruise easily or use a blood-thinning medicine <p>The Pfizer-BioNTech COVID-19 vaccine may not be recommended:</p> <ul style="list-style-type: none"> • In situations of suspected hypersensitivity or non-anaphylactic allergy to COVID-19 vaccine components, investigation is indicated which may lead to immunization in a controlled setting. Consultation with an allergist is advised. • Individuals with previous allergic reaction or breathing problems from the Pfizer-BioNTech COVID-19 vaccine • Individuals who have experienced a serious allergic reaction, including anaphylaxis, to another vaccine, drug or food, should talk to their health professional before receiving the vaccine <p>The medical needs of these patients, including whether or not the administration of a vaccine is appropriate for a patient, are best determined between the patient and their healthcare provider.</p>

Who should not receive the vaccine	Precautions should be taken with:
<ul style="list-style-type: none"> • Individuals who are pregnant and individuals who are breastfeeding until further evidence is available as they were excluded from the clinical trials. • Vaccine should not be offered to individuals who are not in the authorized age group. 	

What are the ingredients in the vaccine?

Non-medical ingredients in the vaccine include:

- ALC-0315 = (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate),
- ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide,
- 1,2-distearoyl-sn-glycero-3-phosphocholine,
- cholesterol,
- dibasic sodium phosphate dihydrate,
- monobasic potassium phosphate,
- potassium chloride,
- sodium chloride,
- sucrose,
- water for injection

It is important to review this list carefully as some people may be allergic to these ingredients, including **polyethylene glycol**. Polyethylene glycol can be found in some products such as cosmetics, skin care products, laxatives, cough syrups, bowel preparation products for colonoscopy, and some food and drinks. The vaccine is packaged in a clear glass vial with a rubber stopper (not made with natural rubber latex).

How is the vaccine administered?

The vaccine is given as a needle in the upper arm (into the deltoid muscle) and will require two doses given 21 days apart.

What are the risks of the vaccine?

Ongoing studies on the Pfizer-BioNTech vaccine indicate **no serious side effects found to-date**. People who have received the vaccine in studies continue to be monitored for any longer-term side effects.

As with other vaccines, **some people can develop mild side effects in the days following immunization that are generally not serious** and go away on their own. In the study, side effects included one or more of the following symptoms: pain where the needle was given, redness and swelling, tiredness, headache, muscle pain, joint pain, chills, mild fever, swollen glands (less frequently). These types of side effects are expected and simply indicate the vaccine is working to produce protection. These side effects are more likely to occur after your second dose.

As with any medicines and vaccines, allergic reactions are rare but can occur after receiving a vaccine. Symptoms of an allergic reaction include hives (bumps on the skin that are often very itchy), swelling of your face, tongue or throat, or difficulty breathing. The clinic staff are prepared to manage an allergic reaction should it occur. If you are concerned about any reactions you experience after receiving the vaccine, contact your health care provider. You can also contact your local public health unit to ask questions or report an adverse reaction.

Can you get COVID-19 from the vaccine?

You cannot get COVID-19 infection from the vaccine. The vaccine is not a live vaccine that does not cause the disease they are designed to prevent.

What measures have been put in place to safely provide immunizations during COVID-19?

Health care providers are being very careful to prevent the spread of COVID-19 when offering immunization. Examples of extra safety measures include the following:

- You will be asked about [any COVID-19 symptoms](#) when you arrive at the clinic. People with symptoms of COVID-19 should not attend the clinic or receive the vaccine.
- You will be asked to wear a mask while at the clinic, as well as to clean your hands, and to stay at least 2 metres (6 feet) from others

- Other measures may also be put in place in clinics. Be sure to read and follow any signs or instructions provided.

What should you do before coming to the clinic?

- Wear a short-sleeve shirt or shirt with sleeves that are easy to roll up.
- To prevent feeling faint while being vaccinated, have something to eat before coming to the clinic.
- Wear your mask.
- Bring any identification required by the clinic, such as your health card.
- Bring your immunization record with you to record this vaccine with other vaccines that you have received.

Before receiving the vaccine, tell the health care provider if:

- If you are currently feeling unwell or have signs and symptoms of COVID-19
- If you are currently breastfeeding.
- If you are or could be pregnant.
- **You have fainted after receiving past vaccines or medical procedures.** Your health care provider may recommend that you receive the vaccine lying down to prevent fainting.
- **You have a bleeding disorder or are taking medication that could affect blood clotting.** This information will help the health care provider prevent bleeding or bruising from the needle.
- If you have had a previous allergic reaction to any vaccine or any non-medical ingredients of the Pfizer-BioNTech COVID-19 vaccine.
- If you have experienced a serious allergic reaction, including anaphylaxis, to another vaccine, drug or food, you should talk to your health professional before you receive the vaccine
- If you are immunosuppressed due to disease or treatment of autoimmune disorder
- When receiving your second dose of COVID-19 vaccine, tell the health care provider if you had **any side effects after the first dose.**
- Have you received any other vaccine (not the COVID-19) in the past 14 days? You will be asked to wait 14 days from the time you received the other vaccine.

What should you do after receiving the vaccine?

You will be asked to **wait at least 15 minutes after receiving** the vaccine to be sure you are feeling well. You may be asked by the health care provider to wait in the clinic, or if an adult is with you and you have a warm, dry place to wait (such as in your vehicle), you may be asked to wait outside of the clinic. Inform a health care provider right away if you feel unwell while waiting. You should not leave the clinic (or clinic parking lot) for at least 15 minutes after receiving your vaccine.

When should I seek medical attention?

Serious side effects after receiving the vaccine are rare. However, should you develop any of the following adverse reactions within three days of receiving the vaccine, seek medical attention right away or call 911 if you are severely unwell:

- hives
- swelling of the face or mouth
- trouble breathing
- very pale colour and serious drowsiness
- high fever (over 40°C)
- convulsions or seizures
- other serious symptoms (e.g., “pins and needles” or numbness).

Do I need to continue to follow public health measures now that I have received the vaccine?

Continue to follow the advice of public health officials to prevent COVID-19, such as wearing a mask, and maintaining a physical distance of 2 metres from people outside of your household.

When can I receive other vaccines?

COVID-19 vaccines should not be given simultaneously with other live or inactivated vaccines.

Do not receive any other vaccines until at least 28 days after you receive the second dose of the COVID-19 vaccine, unless required for post-exposure prophylaxis.

You should wait 14 days after receiving another vaccine before receiving the COVID-19 vaccine.

When should I return for my second dose?

If this is your first dose of the COVID-19 vaccine, be sure to return for your second dose in 21 days. **You should book an appointment to receive the next dose right away.** It is important that you receive 2 doses of the vaccine. Protection against COVID-19 is not complete until after the second dose of vaccine is received.

Bring your immunization record when you come for your second dose in 21 days. **It is very important that you receive the second dose even if you experienced mild side effects the first time.**

Who should I contact with any questions?

If you have any questions, please speak with the person providing the vaccine or contact: